

Amendments to the Specification:

Please add the following new paragraphs after paragraph [0035]:

- [0035.1] FIG.11 Graphs A-D IgG1 Spiking Study.
- [0035.2] FIG.12 Graphs E-H Tg Milk.
- [0035.3] FIG.13 Graph I Feed and Bleed Experiment.
- [0035.4] FIG.14 Graph J Supor Capacity.
- [0035.5] FIG.15 Graph K Milk Concentration v. Liquid Flux Study.
- [0035.6] FIG.16 Graph L Flux v. Milk Concentration Study.
- [0035.7] FIG.17 Graph M Flux v. Temperature.
- [0035.8] FIG.18 Graph N IgG1 Flux v. Flow Velocity.
- [0035.9] FIG.19 Graphs O – P Filtration Assembly.

Please replace paragraph [0087] with the following amended paragraph:

[0087] Experiments using CHO-cell produced IgG1 antibody showed the optimum flow velocity to be approximately 23 cm/s at a trans-membrane pressure of 14 psig (Figure 11 Graph #C & D). However, the feedstream containing the protein or immunoglobulin of interest could be from any source capable of producing such a molecule, including without limitation, transgenic animals producing exogenously derived recombinant proteins. Optimal temperature, according to the current invention, was between 30-35°C (Figure 11 Graph # A). Non-transgenic milk showed liquid flux to be highest at 1.5-2X (Figure 11 Graph # B). When these parameters were tested in a dual TFF system, 82.3% yield was obtained (Figure 11 Graph # H). The flow velocity and trans-membrane pressure experiment was repeated using natural transgenic milk from goat C1017 and showed the optimal flow velocity to be between 40-45 cm/s at a trans-membrane pressure of 16psig (Figure 11 Graph #E & F). The dual TFF process test conducted on natural transgenic milk at the parameters discovered using CHO-cell IgG1 antibody gave a

yield of 64% (Figure 11 Graph #G). The source of transgenic goat could be from any mammal, preferably from an ungulate, and most preferably caprine or bovine in origin.

Please delete Graphs A-D on page 28.

Please delete Graphs E-H on page 29.

Please delete Graph I on page 32.

Please replace paragraph [00100] with the following amended paragraph:

[00100] As seen in Figure 14 Graph J below, Pall Gelman Inc., makes a sterile filter made of Supor membrane with 0.8um prefilter membranes and 0.2um filter membranes combined in a cartridge. These cartridges contain 200 cm², the smallest membrane area available in capsule format for sterile filtration. An experiment was done to determine the filtration capacity of each capsule. Non-transgenic milk was clarified using dual TFF to produce a large quantity of clarified milk that would mimic the feed stream during aseptic processing. A 37 mm disk of Supor membrane was installed in a stainless steel normal flow holder and assembled with a digital pressure transducer and peristaltic pump. USP water was flushed through the entire system to wet the membrane and check for leaks. Clarified non-transgenic milk was then pumped through the system at a constant flow rate, and the pressure was recorded periodically. The data was fit to a line, which related throughput to pressure in the following graph. At 30 psig, the membrane would be plugged therefore throughput was extrapolated to 30 psig to determine capacity. The extrapolated capacity was 7343 ml for a 37 mm disk, which computes to 131 L for a 200 cm² capsule.

Please delete Graph J on page 38.

Please delete Graph K on page 39.

Please replace paragraph [00103] with the following amended paragraph:

[00103] IgG quantitation by protein A HPLC showed that both IgG1 antibody and liquid flux steadily declined with milk concentration. From the Figure 16 graph L below, 1.5 to 2.5 X is reasonable for operating the dual TFF. SDS-PAGE showed no aggregation or degradation due to milk concentration.

Please delete Graph L on page 40.

Please replace paragraph [00104] with the following amended paragraph:

[00104] The IgG1 antibody mass flux through the microfiltration membrane reached a maximum at 27 °C, at 20.3 gm/m²/hr, which is evident in the Figure 17 graph below. The optimum range of operation was 26 °C- 29 °C. Referring to Figure 17 Graph M below, IEF showed no modification of IgG1 antibody isoforms due to processing. SDS-PAGE was uninformative for the milk samples, and the clarified milk samples showed degradation bands. These degradation bands are present in initial milk samples from D035 and are lighter in the TFF clarified bulk material.

Please delete Graph M on page 41.

Please replace paragraph [00105] with the following amended paragraph:

[00105] Each TMP gave an optimum flow velocity, but at 15psi of TMP and 42 cm/s (14lpm) of flow velocity, the IgG1 antibody flux was highest overall. The Figure 18 graph below shows a curve representative of the effects of flow velocity at each transmembrane pressure. IEF showed no change in isoforms due to processing, and SDS-PAGE showed similar results to the previous experiment

Please delete Graph N on page 42.

Please replace paragraph [00106] with the following amended paragraph:

[00106] As seen in Figure 18 Graph N, the first process tests showed a total recovery of 81% of IgG1 antibody from the milk pool. However, about 20% of it was aggregated. The IEF bands looked the same at the end of the clarification as in the initial milk pool. Also, samples from the middle diafiltration volumes showed very low concentrations of IgG1 antibody indicating samples were taken from unmixed areas of the UF feed reservoir. The experiment was repeated.

Please delete Graph P on page 44.

Partial Blank Pages:

On page 27 after paragraph [0087] please insert the following phrase

“The Rest of this Page Left Intentionally Blank”

On page 36 after paragraph [0098] please insert the following phrase

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On page 41 after paragraph [00105] please insert the following phrase

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